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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,604

10/28/2004

Betty M Rozier

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26565 7590 04/17/2007
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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

3772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,604	ROZIER ET AL.	
	Examiner	Art Unit	
	Brandon Jackson	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 2-30 and 40-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/14/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant asserts the filing date of PCT/US03/01216 is 01/15/2003, however the USPTO filing date for PCT/US03/01216 01/16/2003. The USPTO filing date will be used with this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-54, drawn to Figures 1-20, classified in class 128, subclass 877.
- II. Claims 55-60, drawn to Figures 21-22, classified in class 283, subclass 115.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I contains an intravenous site guard with a protective shield and wrap. Group II contains a hand-sizing chart, which is not directly related to the intravenous site guard, is not necessary for the use of the intravenous site guard, and could be used to size a hand for a glove. Group I and II are in now way related in a sense that one is needed in order to use the other.

If applicant selects Group I from above, then an election of species is necessary.

The species are as follows:

Species A: Figures 1a-1e

Species B: Figures 2a-2c

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Species C: Figures 3a-3c

Species D: Figures 4a-4c

Species E: Figures 5a-5d

Species F: Figures 6a-6b

Species G: Figures 7a-7c

Species H: Figure 8

Species I: Figure 9

Species J: Figures 10a-10c

Species K: Figure 11

Species L: Figures 12a-12b

Species M: Figure 13

Species N: Figures 14a-1b

Species O: Figure 15

Species P: Figure 16

Species Q: Figures 17a-1b

Species R: Figures 18a-1b

Species S: Figure 19

During a telephone conversation with Vera Nackovic on 4/4/2007 a provisional election was made without traverse to prosecute the invention of Group I and Species S, claims 1 and 31-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-30 and 40-60 withdrawn from further

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consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 34 and 35 are objected to because of the following informalities: "Velcro ONE-WRAP strap" cannot be claimed because it is a trademark. Therefore, the generic name for the Velcro and the strap must be used. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 34, and 38-39 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,526,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the limitations of Application claim 1 can be found in claim 1 of Patent '981. With respect to claim 34, all the limitation can be found in claims 1-3 of the '981. With respect to claims 38-39, all the limitations can be found in claims 1-5 of '981.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Shesol (US Patent 6,257,240). Shesol, discloses a hollow member (30) having a base (32); an edge positioned upon the patient (fig. 1); hollow member width, height, and length are sufficient to straddle and cover the site (18). The base (32) is joined with the sidewall to form a cover (12). At least one fabric connector (46) is affixed to the hollow member (30). A hook and loop (68), an adhesive (col. 5, lines 36-39), or an ultrasonic bonding (col. 5, lines 36-39) can be used as the means to affix the fabric connector (46) to the hollow member (30). Hook and loop fasteners (52) are the means used to close the fabric connector (46) on the patient (16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) in view of Hely (US Patent 6,142,966). Shesol substantially discloses the claimed invention, see claim 1 rejection above. Shesol fails to disclose at least one opening to accommodate a body part or the first and second opening to accommodate the right and left thumb. However, Hely teaches a wrap (10) comprising a thumbhole (25). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Shesol wrap with a thumbhole, as taught by Hely, because it would prevent the device from moving up and down on the hand. Moreover, It would have been obvious to one of ordinary skill in the art at the time of the invention to add another thumbhole adjacent to the current thumbhole to accommodate a right or left thumb, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240). Shesol substantially discloses the claimed invention; see rejection to claim 1 above. Shesol also discloses a hook and loop means (68) for affixing the wrap (46) to the sidewall of the hollow member (30), which is structurally and functionally equivalent to the Velcro ONE-WRAP strap.

Claims 36-37 rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) in view of Nix (US Patent 5,807,300). Shesol substantially discloses the claimed invention; see rejection to claims 1 and 34 above. Shesol fails to disclose a material selected from the group recited in Claim 34 and

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tubular mesh comprising openings to accommodate various body parts. Nix teaches a wrap (16) made of tubular mesh (col. 1, lines 58-59). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to substitute the undisclosed material of Shesol for the tubular mesh, as taught by Nix, in order to allow air flow and elasticity so the wrap will fit all size hands.

Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) in view of Shultz (US Patent 6,132,399). Shesol substantially discloses the claimed invention; see rejection to claim 1 above. Shesol fails to disclose an agent in the fabric connector and where the agent is selected to be one of antimicrobial, antifungal, antiviral, aloe, vitamin E, and combinations of any of the foregoing. However, Shultz teaches an intravenous securement dressing (10) comprising antimicrobial compound, antifungal compound or vitamins (col. 5, lines 25-28). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Shesol fabric connector with an antimicrobial or antifungal compound in order to aid in the healing in the intravenous site and to prevent infection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cooke (US Patent 3,194,235), Rozier et al. (US Patent 5,167,240), Schaeffer (US Patent 5,577,516), Cook (US Patent 6,322,539).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
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BLJ

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